REMARKS

Claims 1, 5, 23, 30, 38, 45, 46, and 47 have been amended to more clearly define the invention claimed, including the correction of typographical errors. Claims 1-52 are now pending in the application.

No new material is added by this amendment.

Rejections of the Claims under 35 USC § 112:

In the Office Action, the Examiner rejected claims 5 and 23 as lacking antecedent basis for the limitations "the two pieces of tissue" and "the tissue," respectively. Claims 5 and 23 as amended are believed to be in compliance with 35 USC § 112.

Rejections of the Claims under 35 USC § 102:

In the Office Action, the Examiner rejected claims 1, 2, 5-7, 10, 20, 23-25, and 30 as being anticipated by Sterman et al. (U.S. Patent No. 5,814,097). Applicant believes that the claims as amended are believed allowable over Sterman et al., as set forth below.

The Office made reference to a discussion of the Sterman invention, namely columns 15-16, and to Fig. 34a. Applicant notes that the discussion in Sterman at columns 15-16 is directed to Fig. 3, and not to Fig. 34a. The discussion of Fig. 34a takes place at columns 17-18 of Sterman. The device depicted in Fig. 3 and discussed in columns 15-16 is a cardiopulmonary bypass system (including elements 70, 78) in conjunction with an aortic occlusion catheter (element 82) for arresting the heart. (Sterman, col. 15, lines 18-27 and 53-56.) The devices depicted in Figs. 26-34 are "exemplary embodiments of an aortic partitioning system" (Sterman, col. 17, lines 53-55), used to isolate the right atrium and for venous drainage. Sterman is thus directed toward a system for controlling blood flow during a surgical procedure.

Independent claim 1 as amended includes the limitation that the retrograde probe distal portion is positioned adjacent the antegrade probe distal portion. While Fig. 34a of Sterman depicts two probes, there is no teaching or suggestion that the two probes are placed adjacent to each other. Instead, for Figs. 26-34 Sterman teaches that the balloon 414 of the one catheter is adapted to occlude the superior vena cava 416, and the balloon 415 of the other catheter is adapted to occlude the inferior vena cava 417. (Col. 18, lines 9-14, 38-43.) The catheter ends are thus on opposing sides of the right atrium 422, and are not adjacent as required by claim 1. Placing the catheter ends of Sterman adjacent to each other would destroy the utility of Sterman to isolate the right atrium. Accordingly, Sterman teaches away from the invention of claim 1.

Independent claim 30 as amended also includes the limitation that the retrograde probe distal portion is positioned adjacent the antegrade probe distal portion, and is thus allowable in so far as claim 1 is allowable. Claim 30 further recites that the probes are antegrade and retrograde, respectively, to the tissue being repaired. While Sterman has tissue, namely the atrium walls, the catheters of Sterman are not repairing the atrium but are instead merely providing blood flow during a period of cardiac arrest. Accordingly, claim 30 is allowable over Sterman.

Dependent claims 2, 5-7, 10, 20, and 23-25 depend from claim 1, and are thus allowable insofar as claim 1 is allowable. Moreover, many of these dependent claims include additional limitations which can further distinguish them over Sterman.

For example, claim 2 recites the antegrade probe and retrograde probe placed over a common guidewire. By contrast, Sterman has no teaching or suggestion of two probes sharing a common guidewire. Sterman only makes two brief references to guidewires, and the guidewires are never depicted in the figures. The only references to guidewires are where Sterman states that an aortic occlusion catheter "is advanced, usually over a guidewire (not shown) . . . " (Sterman, col. 15, lines 56-57), and that a retroperfusion catheter can be "positioned, usually over a guidewire (not shown) . . . ." (Sterman, col. 16, lines 23-24). Nowhere does Sterman teach or suggest that antegrade and retrograde probes might share a common guidewire.

Claim 2 further includes an antegrade guidewire port and a retrograde guidewire port in alignment. No such alignment is taught by Sterman. The Office has asserted that Fig. 34a of Sterman discloses catheters in alignment. As a first matter, the view of Fig. 34a is not believed to be to scale, and the purported depiction of axial alignment is believed to be the result of convenience to the draftsman. The view is also a two-dimensional view from only one side, which in the absence of further figures and/or description is not believed to teach alignment of the two catheters in real (i.e., 3-dimensional) space. It is particularly notable that such alignment is nowhere referenced in the specification. The specification with respect to Figs. 26-34 describes the balloon 414 of the one catheter occluding the superior vena cava 416, and the balloon 415 of the other catheter occluding the inferior vena cava 417. (Col. 18, lines 9-14, 38-43.) Sterman's catheters 411b and 411c, as depicted in Fig. 34a, are thus each aligned with their corresponding arterial features (i.e., vena cavae 416, 417), and not with the opposing probe. There is no teaching in Sterman that the corresponding arterial features are in alignment, and medical references suggest otherwise. If such alignment between the vena cavae were present, blood flowing from each of the vena cava would be directed toward the other vena cava. However, it is known that blood flowing into the right atrium from the superior vena cava is directed toward the atrioventricular orifice, while the inferior vena cava is directed toward the atrial septum. (Gray, Anatomy of the Human Body, Chapter V, 4b, paras. 16-17, The Heart, 1918 [Exhibit A submitted herewith].) Thus, Sterman's teaching of probes that are aligned with the different vena cava fails to teach probe ports that are aligned with each other.

Claim 10 includes the distal portion being substantially perpendicular to the longitudinal axis of the probe. While the Office has asserted that Sterman depicts such a condition "dependent on where it is in the deployment process," claim 1 from which claim 10 depends includes the limitation that the probe distal portions are adjacent. Sterman provides no teaching that a probe distal portion is perpendicular when the probe distal portions are adjacent each other.

In view of the above discussion, claims 1 and 30 as amended as well as claims 2, 5-7, 10, 20, and 23-25 (which depend from claim 1) are allowable over Sterman.

Rejections of the Claims under 35 USC § 103 over Sterman:

In the Office Action, the Examiner rejected claims 3 and 4 as being obvious over Sterman (U.S Patent No. 5,814,097). Applicant believes that the claims are allowable over Sterman, as set forth below.

As discussed previously in these remarks with respect to the 35 USC § 102 rejection, independent claim 1 as amended recites a system having multiple probes, namely an antegrade probe and a retrograde probe. Additionally, claim 1 recites a portion of the retrograde probe, namely the guidewire port, as being co-aligned with the antegrade probe, and also recites the probe distal portions being adjacent to each other. By contrast, Sterman has no teaching or suggestion of using multiple probes in alignment and adjacent to each other. Accordingly, independent claim 1 as amended is allowable over Sterman. Dependent claims 3 and 4 depend from claim 1, and are thus believed allowable over Sterman. Moreover, claims 3 and 4 each contain additional limitations that further distinguish them over Sterman.

Claim 3 recites a second guidewire, with the antegrade probe having two guidewire lumens and ports, and the retrograde probe having two guidewire lumens and ports. As discussed above with respect to claim 2, Sterman fails to depict any guidewires, and only makes passing reference that a catheter could use a guidewire. Sterman has no teaching or suggestion of a probe using multiple guidewires. Ferrari et al. similarly provides no suggestion toward such a combination of elements. While Sterman and Ferrari et al. discusses that a catheter may have multiple lumens, neither Sterman nor Ferrari et al. makes any suggestion of multiple guidewires.

Claim 4 depends from claim 3 and further recites the first and second guidewires both passing through each of the probes and aligning the distal portions of the probes. While Sterman and Ferrari et al. discuss that multiple lumens may be used in a tubular body, neither Sterman nor Ferrari et al. makes any suggestion that such lumens should be used to accommodate multiple guidewires. Moreover, neither Sterman nor Ferrari et al. provides any teaching or suggestion that multiple probes could share common

guidewires, or that the common guidewires could be used to align antegrade and retrograde probes.

In view of the above, claims 3 and 4 are believed allowable over the cited art.

Rejections of the Claims under 35 USC § 103 over Sterman and Ferrari et al.:

In the Office Action, the Examiner rejected claims 8, 9, 11, 26-28, and 37 as being obvious over Sterman (U.S. Patent No. 5,814,097) in view of Ferrari et al. (U.S. Patent No. 6,190,357). Applicant believes that the claims as amended are allowable over Sterman and Ferrari et al., as set forth below.

As discussed previously in these remarks with respect to the 35 USC § 102 rejection, independent claim 1 as amended recites a system having multiple probes, namely an antegrade probe and a retrograde probe. Additionally, claim 1 recites a portion of the retrograde probe, namely the guidewire port, as being co-aligned and adjacent with the antegrade probe. By contrast, neither Sterman nor Ferrari et al. provides teaching or suggestion of multiple probes that are adjacent and in alignment. Accordingly, independent claim 1 as amended is allowable over Sterman and Ferrari et al, as are claims 8, 9, 1, and 26-28 that depend from claim 1. Claim 37 depends from claim 36, which also includes the limitation of a portion of the retrograde probe, namely the guidewire port, as being co-aligned with an antegrade probe guidewire port. Thus, claim 37 is also believed allowable over Sterman and Ferrari et al. Moreover, claims 8, 9, 11, 26-28, and 37 include further limitations to distinguish them over the art.

Claim 8 recites a vacuum lumen terminating in "at least one vacuum port at said distal portion of said antegrade probe, thereby enabling the grasping and manipulation of tissue." Claim 9 recites similar language, but with the vacuum port on the retrograde probe. No such teaching is present in Sterman or Ferrari et al. Ferrari et al. uses an internal vacuum source only to keep its catheter in a deflated (unexpanded) state. (Ferrari et al., col. 4, lines 63-67; col. 10, lines 3-7; col. 15, line 55 to col. 16, line 6.) No teaching or suggestion is provided of a vacuum port at the distal portion of Ferrari et al., as required by claims 8 and 9. While Ferrari et al. suggests the option of using a

perfusion lumen to apply the vacuum, in such an application Ferrari et al. requires the vacuum to be maintained internally, and suggests applying a one-way valve to the perfusion port to maintain the vacuum. With such a one-way valve in place, no vacuum is presented to the perfusion port. Accordingly, Ferrari et al. actually teaches away from providing a vacuum port as recited in claims 8 and 9.

In view of the above, claims 8, 9, 11, 26-28, and 37 are believed allowable over the cited art.

Rejections of the Claims under 35 USC § 103 over Sterman and Ferrari et al.:

In the Office Action, the Examiner rejected claims 8, 9, 12-19, 21, 22, and 26-52 over Sterman (U.S. Patent No. 5,814,097) in view of St. Goar et al. (U.S. Patent No. 6,629,534). Applicant believes that the claims as amended are allowable over Sterman and Goar et al., as set forth below.

As discussed previously in these remarks with respect to the 35 USC § 102 rejection, independent claim 1 as amended recites a system having multiple probes, namely an antegrade probe and a retrograde probe. Additionally, claim 1 recites a portion of the retrograde probe, namely the guidewire port, as being co-aligned and adjacent with the antegrade probe. By contrast, neither Sterman nor Goar et al. provides teaching or suggestion of multiple probes that are adjacent and in alignment. Accordingly, independent claim 1 as amended is allowable over Sterman and Goar et al.

Because independent claim 1 is allowable over the cited art, claims 8, 9, 12-19, 21, 22, and 26-29 that depend therefrom are also allowable. Moreover, claims 8, 9, 12-19, 21, 22, and 26-29 include further limitations to distinguish them over the art. For example, claims 12-19 depend from claim 1, but further recite one or more tissue fasteners, tissue fastener receivers, and/or tissue fastening lumens at the distal end of a probe. While St. Goar discloses tissue fasteners, there is no teaching or suggestion in St. Goar of using a tissue fastener in conjunction with adjacent retrograde and antegrade probes. Sterman's blood flow control systems similarly provide no teaching or suggestion of the limitations of claims 12-19.

Independent claims 30, 31, and 36 each recites a system having multiple probes, namely an antegrade probe and a retrograde probe. Additionally, claims 30, 31, and 36 each recites a portion of the retrograde probe, namely the guidewire port, as being co-aligned with the antegrade probe. As discussed previously with respect to claim 2, Sterman fails to teach such alignment. Sterman's catheters 411b and 411c, as depicted in Fig. 34a, are each aligned with their corresponding arterial features (i.e., vena cavae 416, 417), and no mention is made of alignment with the opposing probe. There is no teaching in Sterman that the corresponding arterial features are in alignment, and medical references suggest otherwise. St. Goar et al. fails to teach multiple probes, much less probes in alignment. Claim 30 as amended also recites portions of the probes being adjacent, which is not taught by the cited art. Accordingly, independent claims 30, 31, and 36 are allowable, as are dependent claims 32-35 and 37 which depend therefrom.

Independent claim 38 as amended recites a method of stabilizing tissue, comprising delivering antegrade and retrograde probes to the tissue from antegrade and retrograde approaches, aligning the probes longitudinally, using one or more of the probes to stabilize the tissue, and using one or more of the probes to fasten the tissue. Sterman's teaching of blood flow controlling devices, and St. Goar's teaching of a single catheter for treating tissue, provides no suggestion of multiple aligned probes, much less of the method of claim 38. Claim 38 is thus believed allowable over the cited art.

Claims 39-52 depend from claim 38, and thus are also allowable over Sterman and St. Goar et al. Claims 39-52 also include further limitations which further distinguish them over the art. For example, claim 39 recites the probes as providing support for tissue interposed therebetween. No such teaching is present in Sterman or St. Goar et al. Claim 40 recites the method as being completed without arresting the patient's heart, which is in direct contrast to the sections of Sterman cited by the Office. For example, Fig. 3 of Sterman depicts an occluding catheter "for purposes of arresting cardiac function." (Sterman, col. 15, line 53.) Fig. 34a involves a system for use when "inducing cardioplegia in the heart." (Sterman, col. 17, line 58.) Thus, Sterman the cited portions of Sterman actually teach away from claim 40.

Claim 41 recites using the guidewire to pierce the atrial septum, advancing the guidewire to pass through the mitral valve and out an exit point, advancing the antegrade probe over the guidewire through the entry point to the mitral valve, and advancing the retrograde probe over the guidewire through the exit point to the mitral valve. While St. Goar et al. teaches using a single catheter in procedures performed through the septum, there is no teaching or suggestion in St. Goar et al. or Sterman of using antegrade and retrograde probes in combination as recited in the claims.

Claim 42 recites aligning the probes to interact to provide stabilizing support to the tissue. No such alignment or interaction is taught or suggested by St. Goar et al. or Sterman.

Claims 43-52 provide further limitations concerning the tissue and procedures involved. They also include the limitations of claim 38, namely the use of multiple probes to stabilize and fasten tissue. As discussed previously, St. Goar et al. and Sterman fail to provide such teaching. Accordingly, the claims are allowable over the cited art.

CONCLUSION

Applicant believes all claims are in condition for allowance, and respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

Dated: 7/6/04
July 6, 2004

John Christopher James, PTO Reg. No. 40,660
Edwards Lifesciences LLC
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6878
Facsimile: (949) 250-6850
CUSTOMER NO.: 30452

toward the atrioventricular orifice, while that entering through the inferior vena cava is directed upward and backward, toward the atrial septum. This is the normal direction of the two currents in fetal life.

The **coronary sinus** opens into the atrium, between the orifice of the inferior vena cava and the atrioventricular opening. It returns blood from the substance of the heart and is protected by a semicircular valve, the **valve of the coronary sinus** (*valve of Thebesius*). 18

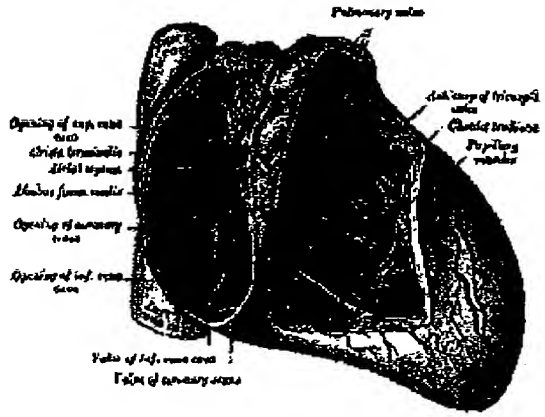

FIG. 493– Interior of right side of heart. (See enlarged image)

The **foramina venarum minimarum** (*foramina Thebesii*) are the orifices of minute veins (*venæ cordis minimæ*), which return blood directly from the muscular substance of the heart. 19

The **atrioventricular opening** (*tricuspid orifice*) is the large oval aperture of communication between the atrium and the ventricle; it will be described with the right ventricle. 20

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The valve of the inferior vena cava (*valvula venæ cavæ inferioris* [*Eustachii*]; *Eustachian valve*) is situated in front of the orifice of the inferior vena cava. It is semilunar in form, its convex margin being attached to the anterior margin of the orifice; its concave margin, which is free, ends in two cornua, of which the left is continuous with the anterior edge of the limbus fossæ ovalis while the right is lost on the wall of the atrium. The valve is formed by a duplicature of the lining

EXHIBIT A

groove, the **terminal sulcus,** which extends from the front of the superior vena cava to the front of the inferior vena cava, and represents the line of union of the sinus venosus of the embryo with the primitive atrium. On the inner wall of the atrium the separation is marked by a vertical, smooth, muscular ridge, the **terminal crest.** Behind the crest the internal surface of the atrium is smooth, while in front of it the muscular fibers of the wall are raised into parallel ridges resembling the teeth of a comb, and hence named the **musculi pectinati.**

Its interior (Fig. 493) presents the following parts for examination:

- Superior vena cava.
- Inferior vena cava.
- Coronary sinus.
- Openings »
  - Foramina venarum minimarum.
  - Atrioventricular.
- Valves »
  - Valve of the inferior vena cava.
  - Valve of the coronary sinus.
  - Fossa ovalis.
  - Limbus fossæ ovalis.
  - Intervenous tubercle.
  - Musculi pectinati.
  - Crista terminalis.

The **superior vena cava** returns the blood from the upper half of the body, and opens into the upper and back part of the atrium, the direction of its orifice being downward and forward. Its opening has no valve.

The **inferior vena cava,** larger than the superior, returns the blood from the lower half of the body, and opens into the lowest part of the atrium, near the atrial septum, its orifice being directed upward and backward, and guarded by a rudimentary valve, the **valve of the inferior vena cava** (*Eustachian valve*). The blood entering the atrium through the superior vena cava is directed downward and forward, *i.e.*,

EXHIBIT A